

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 265.00410201		Date of mailing (day/month/year) 21 SEP 2003	
International application No. PCT/US04/40120		FOR FURTHER ACTION See paragraph 2 below	
International filing date (day/month/year) 01 December 2004 (01.12.2004)	Priority date (day/month/year) 01 December 2003 (01.12.2003)		
International Patent Classification (IPC) or both national classification and IPC IPC(7): C07H 21/02, 21/04; C12P 19/34, 10/0221/00; C12N 15/09, 15/82, 15/85, 15/00; C12Q 1/70, 1/68, 33/48 and US Cl.: 536/23.1, 23.72; 435440, 441, 442455, 91.1, 91.4, 91.4291.51, 69.1, 69.270.1, 455, 5, 6, 94			
Applicant BOARD OF REGENT, THE UNIVERSITY OF TEXAS SYSTEM			

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

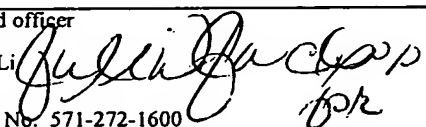
2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Bao Qun Li  Telephone No. 571-272-1600
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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

I. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☐ claims Nos. _____

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐

has not been furnished

☐

does not comply with the standard

the computer readable form

☐

has not been furnished

☐

does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>37</u>	YES
	Claims <u>1-36</u>	NO
Inventive step (IS)	Claims <u>37</u>	YES
	Claims <u>1-36</u>	NO
Industrial applicability (IA)	Claims <u>1-37</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-36 lack novelty under PCT Article 33(2) as being anticipated by Wimmer et al. Wimmer et al. disclose an efficient HCV replicon comprising a mutation at 2204 and a method for using the polynucleotide encoding the replicon comprising the sequence encoding genes encoding HCV core, E1, E2, P, NS2, NS3, NS4A, NS4B, NS5A and NS5B, wherein the HCV genome is derived from HCV genotype 1a. The claimed polynucleotide sequence if possible, can be used for screening an anti-HCV compound. (entire documents, especially, Figs. 2-4, columns 6-7, claim 1-52).

Claims 1-2, 7, 9-10 and 14-17, lack novelty under PCT Article 33(2) as being anticipated by Buhk et al. Buhk et al. teach that particular point mutation(s) in HCV coding sequence can permit the HCV RNA replicate more efficiently in the Huh-7 cells, wherein one of the mutation includes the mutation at the amino acid residue 2204. The mutated HCV polynucleotide can be used for efficiently replication of HCV genome.

Claim 36 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest to make a kit comprising the particular mutated HCV polynucleotide for making HCV replicon.

Claims 1-37 meet the criteria set out in PCT Article 33(4), and thus, the particular isolated HCV mutant polynucleotide can be used for an industrial applicability because the subject matter claimed can be made or used in industry.